

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION <hr/> THIS DOCUMENT RELATES TO: <i>Veronica Madsen et al. vs. C.R. Bard, Inc.</i> Case No. 2:16-cv-11633	MDL No. 2187 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**PLAINTIFFS' OPPOSITION TO C.R. BARD, INC.'s
MOTION FOR PARTIAL SUMMARY JUDGMENT**

INTRODUCTION

Genuine disputes of material fact preclude summary judgment on Plaintiffs' claims for negligence based on failure to warn (Count I), strict liability based on failure to warn (Count IV), and punitive damages (Count VIII).

Defendant does not seek summary judgment on Plaintiffs' claims for negligence based on design defect (Count I), strict liability based on design defect (Count II), and loss of consortium (Count VII).

Plaintiffs do not oppose summary judgment on their claims for negligence based on manufacturing defect (Count I), strict liability based on manufacturing defect (Count III), breach of express warranty (Count V), and breach of implied warranty (Count VI).

STANDARD ON SUMMARY JUDGMENT

The Court may enter summary judgment only if the defendant shows there is no genuine

issue as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). The Court must not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Rather, the Court must draw any permissible inference from the underlying facts in the light most favorable to plaintiff. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

ARGUMENT

I. Choice of Law

Plaintiffs agree that Illinois choice of law principles apply. Plaintiffs also agree that under Illinois’ choice of law principles, the substantive law of Illinois applies to Plaintiffs’ claims for negligence, strict liability, loss of consortium, and punitive damages.

II. Disputes of Material Fact Preclude Summary Judgment on Plaintiffs’ Failure to Warn Claims

Defendants seek summary judgment on Plaintiffs’ warnings claims on one and only one basis: that Mrs. Madsen’s implanting physician knew the risks and complications of the Align TO. (Doc. 81, Memo in Support of Mot. at 6.) However, disputes of material fact about this preclude summary judgment.

Plaintiff sustained injuries as the result of the Align TO. Specifically, after the implantation, Plaintiff developed i) de novo overactive bladder symptoms, ii) recurrent stress urinary incontinence, iii) vaginal pain, iv) bilateral pelvic nerve pain and numbness, and v) pain in her legs and thighs. (Ex. A, Rule 26 Case Specific Report of Michael Margolis, M.D. at 17-18.) The Align TO and its effects, including shrinkage/contraction, on Mrs. Madsen’s surrounding tissues were the cause of Mrs. Madsen’s injuries. (*Id.* at 18.) Mrs. Madsen continues to suffer from these injuries

and will suffer from at least some of these injuries permanently. (*Id.* 18-19.) She will also suffer chronic foreign body reaction and chronic inflammation of the surrounding tissues as a result of the flawed characteristics of the Align TO. (*Id.*)

The record supports the inference that the implanting physician, Dr. Upputuri, was unaware of these risks. Dr. Upputuri's practice was to warn her patients of *all significant risks* related to a proposed surgical procedure. (Ex. D. to Mot., Upputuri Dep. 26:23-27:2.) Dr. Upputuri did not warn Mrs. Madsen about several significant risks, including the risk of chronic pelvic pain (Ex. B, Madsen Dep. at 145:2-6), chronic pain with sexual intercourse (*id.* at 145:14-17), chronic vaginal infection (*id.* at 146:1-4), chronic urinary tract infections (*id.* at 146:13-16), chronic groin pain (*id.* at 147:13-16), chronic thigh pain (*id.* 148:1-4), chronic leg pain (*id.* at 148:15-18), chronic nerve pain (*id.* at 149:3-6), chronic foreign body reaction (*id.* at 150: 11-16), degradation (*id.* at 151:5-8), and shrinkage (*id.* at 151:17-20.) Because Dr. Upputuri's practice was to warn her patients of all significant risks, and because she did not warn Mrs. Madsen of these significant risks, it stands to reason that she was unaware of these significant risks. The facts permit this inference, which is sufficient to defeat summary judgment.

To establish Dr. Upputuri knew all the risks, Defendant relies on testimony that Dr. Upputuri typically discussed the following risks with her patients before implanting a sling: pain, failure, erosion, urinary retention, bladder perforation, infection, bleeding, hematomas, and dyspareunia. (Doc. 81, Memo in Support of Mot. at 7-9.) Other than pain and pain during intercourse, these are not the risks Mrs. Madsen experienced. Moreover, merely warning about the risks of the *surgery* is different from warning about the risks of the *mesh*. For example, virtually any surgery involves temporary post-operative pain, so the fact Dr. Upputuri warned Mrs. Madsen about

“pain” does not show Dr. Upputuri was aware of the risk of chronic pain associated with the mesh. To the contrary, as shown in the preceding paragraph, there is evidence Dr. Upputuri was unaware of many of the risks Mrs. Madsen experienced.

In addition to evidence that Dr. Upputuri was unaware of substantial risks of the Align PO, the record is replete with evidence that Dr. Upputuri was unaware of numerous other issues with the Align TO. Prior to implantation, Defendant did not inform Dr. Upputuri of the rate and duration of risks associated with the Align TO. (Ex. D to Motion, Upputuri Dep. 33:13-22.) Had Defendant warned Dr. Upputuri of any risk rates higher than three percent, that warning would have impacted her decision to use the Align TO. (*Id.* at 34:9-35:1.)

Next, Defendant did not inform Dr. Upputuri that the mesh products on the market were overengineered with regard to strength for their biologic requirement. Had Defendant warned Dr. Upputuri of this, the warning would have impacted her decision to use the Align TO. (*Id.* at 35:18-36:2.)

Further, Defendant did not warn Dr. Upputuri that the pore size of mesh on the market resulted in a formation of a scar plate that was rigid and does not integrate well over time with the host tissue. Had Defendant warned Dr. Upputuri of this, the warning would have impacted her decision to use the Align TO. (*Id.* at 36:3-37: 20.)

Additionally, Defendant did not warn Dr. Upputuri that a more light-weight open-pore mesh was needed. Had Defendant warned Dr. Upputuri of this, the warning would have impacted her decision to use the Align TO. (*Id.* at 37:21-38:8.)

Next, Defendant did not warn Dr. Upputuri that the shrinkage rate for mesh on the market was between 30 and 50 percent. Had Defendant warned the implanting physician of this, the

warning would have impacted her decision to use the Align TO. (*Id.* at 38:4-19.)

Further, Defendant did not warn Dr. Upputuri that the polypropylene used in the Align TO was specifically not for use in medical applications involving permanent implantation in the human body. Had Defendant warned the implanting physician of this, the warning would have impacted her decision to use the Align TO. (*Id.* at 38:2-39:2-7.)

Also, Defendant did not warn Dr. Upputuri that the Align TO creates a scar plate that is rigid, preventing the product from integrating well over time with the host tissue. Had Defendant warned Dr. Upputuri of this, she would have passed that warning on to Mrs. Madsen. (*Id.* at 39:8-18.)

Defendant did not warn Dr. Upputuri that mesh shrinkage of 30 to 50 percent postimplantation directly resulted in scar plate formation. Had Defendant warned Dr. Upputuri of this, she would have passed that warning on to Mrs. Madsen. (*Id.* at 39:18-40:4.)

Defendant did not warn Dr. Upputuri that the polypropylene used to create the Align PO was not indicated for permanent human implantation. Had Defendant warned Dr. Upputuri of this, Dr. Upputuri would have passed that warning on to Mrs. Madsen. (*Id.* at 40:5-13.)

Because material facts are in dispute about whether Mrs. Madsen's implanting physician knew the risks and complications of the Align TO, Defendant's motion for summary judgment on the warnings claims fails.

III. Disputes of Material Fact Preclude Summary Judgment on Plaintiff's Claim for Punitive Damages

Defendant contends Illinois law governs Plaintiffs' claim for punitive damages. Under Illinois law, punitive damages are available where torts are committed with such gross negligence as to indicate a wanton disregard of the rights of others. *Loitz v. Remington Arms Co., Inc.*, 138 Ill. 2d

404, 415 (1990). Willful and wanton misconduct may be only degrees more than ordinary negligence. *Ziarko v. Soo Line Railroad Company*, 161 Ill. 2d 267, 275-76 (1994).

Disputes of material fact preclude summary judgment on Plaintiffs' claim for punitive damages. The Material Safety Data Sheet (MSDS) for the Marlex HGX-030-01 used by Bard to create the Align products contains a warning regarding degradation that states, "Incompatibility With Other Materials: May react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc." (Ex. C, Rule 26 Expert Report of Anthony B. Brennan, PhD. at 16.) In addition, Bard knew that the polypropylene material used to manufacture the mesh contained a "MEDICAL APPLICATION CAUTION" in the MSDS which stated, "Do not use this [] material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." (Ex. D, Rule 26 Expert Report of Alan Garely, M.D. at 11.) A Phillips Sumika Marlex HGX-030-01 information sheet listed the following as suggested uses for the particular polypropylene grade: Woven industrial fabric and bags, rope and cordage, woven carpet backing, and geotextile fabrics. (*Id.*) These facts, if proven at trial, are sufficient to establish such gross negligence as to indicate a wanton disregard of the rights of others. (*Id.*)

These same disputed material facts preclude summary judgment on Plaintiffs' claims for punitive damages if New Jersey substantive law applies to that claim. The focus of the punitive damages inquiry, Bard's corporate conduct, allegedly occurred in New Jersey. Bard is a New Jersey corporation with its principal place of business in New Jersey. (Doc. 351-4, Bard Answer to Plaintiffs' Master Long Form Complaint and Jury Demand at ¶ 3 in 2:10-md-02187.) Accordingly, New Jersey law could apply to Plaintiffs' claim for punitive damages. *Huskey v.*

Ethicon, Inc., 29 F. Supp. 3d 736, 741 (S.D.W. Va. 2014).

Under New Jersey law, punitive damages are proper when a manufacturer is “(1) aware of or culpably indifferent to an unnecessary risk of injury, and (2) refuses to take steps to reduce that danger to an acceptable level.” *Fischer v. Johns-Manville Corp.*, 103 N.J. 643, 670–71 (1986).

This standard can be met by a showing of “a deliberate act or omission with knowledge of a high degree of probability of harm and reckless indifference to consequences.” *Id.* The evidence that bars summary judgment under Illinois law also bars summary judgment under the New Jersey standard for punitive damages.

CONCLUSION

For the reasons stated, Plaintiffs pray this Court deny Defendant’s Partial Motion for Summary Judgment and grant such further relief as is proper.

Dated: March 3, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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